



MISSOURI DEPARTMENT OF MENTAL HEALTH

DORN SCHUFFMAN, DEPARTMENT DIRECTOR



DEPARTMENT
OPERATING
REGULATION
NUMBER

DOR

1.230

CHAPTER General Department	SUBCHAPTER Department Operations	EFFECTIVE DATE 1/1/2004	NUMBER OF PAGES 6	PAGE NUMBER 1 of 6
SUBJECT Internal Regulation Process		AUTHORITY 536.014, 536.016, 536.025, 536.026 and 630.050 RSMo	HISTORY See below	
PERSON RESPONSIBLE Deputy Director, Office of Quality Management			SUNSET DATE 7/1/2007	

PURPOSE: Describes how the department will implement its authority to promulgate administrative rules and department operating regulations.

Application: Applies to the entire department.

(1) Definitions:

(A) Administrative Rule, a regulation that affects providers and other entities outside the department of mental health;

(B) Department Operating Regulation (DOR), a regulation that affects employees of the department and facilities operated by the department;

(C) Executive Team, division directors and other senior administrative staff designated by the department director;

(D) Fiscal Note, a statement estimating the cost of a proposed regulation resulting from its implementation;

(E) Regulation, an administrative rule or department operating regulation (DOR);

(F) Regulation Author, a department employee who is responsible for writing a regulation;

(G) Regulation Owner, the program division or office with the primary responsibility for a regulation;

(H) Regulation Review Team, department staff whose collective duty is to oversee the department's responsibility to develop and monitor regulations;

(I) Regulation Summary Sheet, a DMH form on which a regulation author summarizes a draft regulation for review by the Regulation Review Team;

(J) Regulatory Process Coordinator(s), staff within the Office of Quality Management designated to provide technical assistance, consultation, oversight, and quality improvement relative to regulation development and to serve as coordinating staff to the Regulation Review Team; and

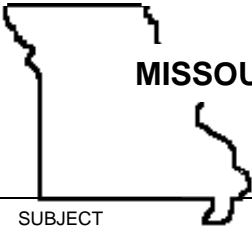
(K) Sunset, the date on which a DOR expires unless renewed through the regulatory development process.

(L) Under Timelines, the terms represent the following.

1. Assessment Phase, this phase refers to the initial development of the regulation and concludes with formal approval by both the Regulation Review Team and the Office of Administration (DMH).

2. Expedited Process Phase, the abbreviated process of amending an existing DOR by the use of an abbreviated Regulation Summary Sheet and the elimination of comment procedures.

3. Process Phase, this phase refers to the formal distribution period of a proposed regulation for comment.



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4. Final Phase, this phase refers to the point after all comments are considered until the point at which the final regulation is official.

(2) Regulation Review Team.

(A) The membership of the Regulation Review Team shall be as follows:

1. Two persons from each division appointed by division director;
2. Two persons appointed by the department director;
3. The department's general counsel;
4. The department's legislative liaison;
5. The department's regulatory process coordinator(s) who serve as non-voting staff; and
6. Ad hoc consultants recruited by the team on an as-needed basis.

(B) The Regulation Review Team shall meet monthly; the general counsel and legislative liaison are non-voting members and are not required to attend the meetings in person, but the coordinator shall keep them abreast of the team's activities.

(C) A quorum is required at each meeting. A quorum shall consist of –

1. At least one member from each division;
2. At least one member appointed by the director; and
3. Any ad hoc consultant considered by the committee to be a necessary participant, except that the consultant may participate in writing, by e-mail or by telephone.

(D) Duties of the Regulation Review Team shall include –

1. Reviewing the direction and purpose of the department's regulatory responsibilities on an ongoing basis;
2. Reviewing each new regulatory initiative;
3. Approving or disapproving each new regulatory initiative with respect to its necessity. Each program division and the director's office shall have one vote on regulatory necessity;
4. Discussing pending regulatory developments, imminent timelines and related issues;
5. Reviewing fiscal impact statements;
6. Evaluating the effectiveness of the department's regulations and the effectiveness of the Regulation Review Team process; and
7. Providing the Executive Team with annual reports related to quality assurance.

(3) Duties of the Regulatory Process Coordinator(s) are -

- (A) Issuing regulation numbers;
- (B) Preparing cover letters, affidavits and transmittal sheets for the filing of a rule or the departmental review of a DOR;
- (C) Issuing alerts and reminders to regulation owners regarding filing timelines and requirements;



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(D) Identifying the sunset date for each regulation, i.e. the first day of July following thirty-six months after the effective date;

(E) Providing technical assistance, consultation and review with respect to regulatory consistency, formatting, language, and style;

(F) Identifying and analyzing new regulatory issues (e.g. legislation, court decisions) for the Regulation Review Team and the deputy director of the Office of Quality Management, and carrying forward the team's recommendation;

(G) Circulating regulation summary sheets and other information as may be appropriate to the executive team, the mental health commission, the governor's office, and others to whom the information may be relevant;

(H) Providing coordination and support to the Regulation Review Team, including scheduling meetings, preparing agenda, and facilitating meetings; and

(I) Preparing and circulating the minutes of each meeting to the regulation owners, the executive team, and other interested parties.

(4) Each regulation owner shall assign staff for rule drafting and fiscal note development. Fiscal notes shall be developed in accordance with DOR number 1.235.

(5) Responsibilities of the Regulation Author.

(A) Obtaining authorization from a regulation owner to write a regulation;

(B) Gathering empirical evidence as may be reasonably available to indicate that a regulation is necessary, submitting this information to the Regulation Review Team, and retaining records of this evidence on file;

(C) Obtaining input regarding the content of the regulation from –

1. Staff who will be required to implement the regulation;
2. Consumers who will be affected by the regulation; and
3. Others who will be significantly affected by the regulation.

(D) Obtaining a regulation number from the regulatory process coordinator(s);

(E) Preparing a regulation summary sheet and submitting it to the regulatory process coordinator(s);

(F) Developing a fiscal note (for administrative rules) or arranging for the development of a fiscal note;

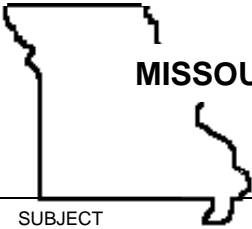
(G) Submitting the fiscal note to Office of Administration (DMH) for approval. A copy of the draft regulation shall accompany fiscal notes submitted for approval; and

(H) Coordinating revisions to a proposed regulation in response to comments received.

(6) Regulation Review Criteria Used by the Regulation Review Team.

(A) The following criteria guide the deliberations and recommendations for both rules and DORs.

1. The regulation is consistent with existing regulations and statutes.
2. The regulation is consistent with other department initiatives, its core mission, values and strategic plan.
3. The regulation is in the proper form (rule versus DOR, policy/procedure).



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4. The constituencies who will be affected by the regulation have been identified and have had the opportunity to provide input.

(5) The regulation reflects wise and legal use of public funds.

(6) The regulation is consistent with ethical conduct.

(B) If the regulation is a DOR, the Regulation Review Team shall determine whether or not the DOR meets at least one of the following criteria.

1. The DOR is necessary to establish needed consistency across facilities, divisions and offices operated by the department.

2. The DOR is necessary to meet requirements established by external accreditation or certification organizations.

3. The DOR is necessary to comply with a state or federal statute, administrative rule or an oversight review.

(C) If the regulation is an administrative rule, it must meet all of the following criteria.

1. There is statutory authority for the promulgation of the rule.

2. The rule is not in conflict with state law.

3. There is substantial evidence on the record that the rule is necessary to carry out the purpose of the statute that granted such rulemaking authority. The evidence must be empirical and reasonably available.

4. The rule does not result in substantial inequity as to be unreasonably burdensome on persons affected.

5. Fiscal notes have been approved.

6. The requirements of Executive 03-15 have been addressed.

(7) Disposition of a Regulation by the Regulation Review Team.

(A) The Regulation Review Team shall advise the author whether the proposed regulation meets the criteria described in section (6).

(B) If the author and the Regulation Review Team disagree and cannot resolve differences, the matter shall be referred to the appropriate division director(s) or deputy director. That opinion shall prevail.

(C) If more than one division director or deputy director is involved and cannot reach consensus, the matter shall be referred to the department director. That opinion shall prevail.

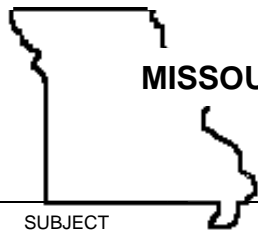
(8) Timelines for Regulation Development, amendment and rescission.

(A) Assessment Phase.

1. The regulation author shall submit the regulation summary sheet and other supporting documentation to the regulatory process coordinator(s).

2. Within thirty working days of receiving a regulation summary sheet, the Regulation Review Team shall either approve or disapprove the regulation with regard to its necessity.

(B) Process Phase.



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1. The regulation author shall submit the regulation to the regulatory process coordinator(s) and the fiscal note (administrative rules only) to the DMH Office of

Administration. The Office of Administration shall either approve or disapprove a fiscal note within ten working days of receiving it.

2. If the regulation is an administrative rule, the process phase begins with the filing of a Proposed Rulemaking with the Joint Commission on Administrative Rules.

3. If the regulation is a DOR, the process phase begins when the regulatory process coordinator(s) distributes the DOR for first review.

a. The process phase entails two review periods except –

(i.) It may be finalized after one review period and after considering the comments if the only changes are minor in nature and do not substantively alter the DOR as proposed. Examples of minor changes include, but are not limited to changes in format, grammar, spelling, syntax, and word clarification.

(ii) If substantive differences remain after two comment periods, additional comment periods may be necessary.

(iii) Regulation authors may consult with the regulatory process coordinator(s) for guidance. At each review, the period to make comments shall be ten working days.

b. At each review the period to make comments shall be ten working days.

(C) Expedited Process Phase. The Regulation Review Team may exempt a DOR amendment from the Process Phase if the following requirements are met{+} .

1. The regulation author has completed an internal review of the DOR{+} .

2. The regulation author has requested the exemption [~~+~~and] .

3. The proposed revisions meet one of the following criteria.

A. They simply codify existing state or federal statute.

B. They replicate changes in other state regulations, such as those published by the state Office of Administration;

C They are not substantive. In this context, the following are considered not substantive:

(I) Revisions in spelling, syntax, grammar;

(II) Changes in formatting or organization;

(III) Addition of provisions related to quality assurance, quality improvement and failure to comply; and

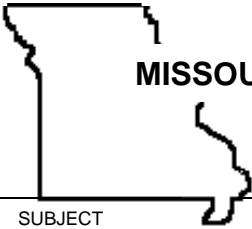
(IV) Corrections of references to other documents.

(D) Final Phase.

1. If the regulation is an administrative rule, the final phase begins when an Order of Rulemaking is filed with the Joint Commission on Administrative Rules.

2. If the regulation is a DOR, the final phase begins when the author submits the final version to the regulatory process coordinator(s).

(E) If a regulation is not promulgated within one year of the submission of the regulation summary sheet to the Regulation Review Team, the regulation author must submit a revised regulation summary sheet for the Regulation Review Team.



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(9) Emergency Regulations.

(A) At the request of a regulation owner, the Regulation Review Team shall convene emergency meetings on any proposed regulation that requires immediate attention. Examples of emergency situations requiring prompt action are those that –

1. Address an immediate danger; or
2. Preserve a compelling governmental interest that requires an immediate effective date such as meeting a state or federal regulatory requirement or meeting a funding requirement.

(B) The Regulation Review Team may authorize an emergency regulation to be put into effect immediately for a period not to exceed 6 months.

(10) Provisions for Quality Assurance. At the time a DOR is created, amended or reviewed under the sunset requirements, text shall be introduced to include provisions for the owner to periodically review the activities required by the DOR for the purpose of identifying trends patterns, and possible means of improvement.

(11) In June of each year the Regulation Review Team shall review the regulatory process and the functions of the Regulation Review Team and submit a report of its findings.

History: Original effective date Aug. 15, 2001. Amendment effective July 15, 2002. Amendment effective January 1, 2004.